UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Q-MED AB,

Plaintiff,

- against -

HA NORTH AMERICAN SALES AB, MEDICIS AESTHETICS HOLDINGS INC., and MEDICIS PHARMACEUTICAL CORP.,

Defendants.

12 Civ. 8071 (RJS)

DECLARATION OF DR. MITCHELL S. WORTZMAN, PH.D., IN SUPPORT OF DEFENDANTS' OPPOSITION TO Q-MED AB'S MOTION FOR PRELIMINARY INJUNCTION

MITCHELL S. WORTZMAN, declares under penalty of perjury, pursuant to 28 U.S.C. § 1746, as follows:

1. I am currently employed as Executive Vice President and Chief Scientific Officer with Medicis Pharmaceutical Corporation ("Medicis"). I submit this declaration in support of Defendants' Opposition to Q-Med AB's Motion for Preliminary Injunction.

2. I have been employed by Medicis since August 1997, and have held my current position since July 2003. During my tenure at Medicis, I have been part of the conception and development of Company products and hold numerous patents on these products. I participate in the Q-Med/Medicis Joint Steering Committee ("JSC"), which meets periodically to discuss the ways in which Medicis markets Q-Med's products.

3. Prior to joining Medicis, I worked for seventeen years at Neutrogena Corporation. From 1989 to 1997, I served as President of Neutrogena's

Dermatologics Division. I have an undergraduate degree in biochemistry from the State University of New York at Stony Brook and a Ph.D. in cellular and molecular biology from the University of Southern California. I am also a member of several professional organizations in Dermatology, including the American Academy of Dermatology and the Society for Investigative Dermatology.

4. I am fully familiar with the various dermal fillers on the market, including the highly popular Restylane family of hyaluronic acids ("HA's"); their competitors, the Juvederm family of products; fringe players in the HA market like Elevess and Succeev; and bio-stimulating particle fillers like Sculptra.

5. I understand that Q-Med is seeking to enjoin Medicis from proceeding with the intended merger with Valeant based on, among other things, the argument that Valeant's products, principally Sculptra, are directly competitive to those marketed by Medicis. I have reviewed the papers submitted by Q-Med in connection with its request for a preliminary injunction with particular focus on the declaration of Mr. Per Langö, who also participates on the Q Med/Medicis Joint Steering Committee.

6. I strongly disagree with the assertion that Valeant's products, principally Sculptra, compete directly with the Restylane family of fillers marketed by Medicis. As I set out in the balance of this declaration, the scientific properties of the products are different, the products are used in different and often complementary ways, and achieve different results.[1] Each of these factors, in my judgment, undermines Q-

[1] This Declaration is submitted to address whether certain products are competitive in the marketplace. As such, I set forth my understanding concerning how the products are actually used by practitioners. While Medicis does not market to, or encourage, off-label marketing in any way, and in fact has strict compliance policies against it, I

Med's claim that the dermal filler products marketed by Valeant compete directly with the Restylane family of fillers.

Hyaluronic Acid Dermal Fillers.

7. Restylane is produced by Q-Med and marketed by Medicis in the United States under a licensing agreement that I understand to be at the center of Q-Med's request for a preliminary injunction. Restylane is an HA filler. HA is a molecule that exists in nature and is identical in all living beings including humans. Restylane is a cross-linked HA in gel form that is used, for example, to treat facial wrinkles and folds, as well as lip augmentation. After a period of time, generally about 6 months, patients injected with Restylane begin to perceive the need for retreatment.

8. Restylane was the first of the modern injectable dermal fillers, and replaced collagen for cosmetic uses in areas of the face below the nose. In 2003, the United States Food and Drug Administration ("FDA") approved Q-Med's premarket approval application ("PMA"). The initial approved indication was "for mid-to-deep dermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds [the lines from the nose to the corners of the mouth]." Attached hereto as Exhibit A is a true and correct copy of the FDA Approval Letter for Restylane. In 2011, the FDA approved Medicis's PMA supplement to expand the approved use to include lip augmentation. The new label includes an indication for submucosal implantation for lip augmentation in patients over the age of 21.

9. Another member of the Restylane family is Perlane, an HA dermal filler also produced by Q-Med and marketed in the United States by Medicis, which was

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provide this evidence as to how the products are actually used in clinical practice to

approved by the FDA in 2007. Perlane is formulated to a larger particle size than Restylane, and thus is injected deeper in the skin with a slightly larger needle. Perlane is generally used for deeper wrinkles whereas Restylane is generally used in more superficial layers where the ability for the product to flow freely is more desirable, as in lips or the hollow under the eye.

10. Another member of the Restylane family is Restylane SubQ. SubQ, like the others, is an HA filler produced by Q-Med. SubQ is similar to the other members of the Restylane family but has even greater particle size than the other two and thus is primarily used for deeper injections and more significant volumizing. SubQ, however, is not marketed in the United States or Canada because it failed to meet criteria required for a commercially viable product and unless Q-Med can remedy such failures (and indeed, Q-Med owes Medicis a working product under the 2004 agreement), there is no prospect of it being marketed by Medicis for the foreseeable future.

11. SubQ was approved for use in Europe, and subsequently, Medicis introduced the product to Canada, where testing with key opinion leaders produced decidedly mixed results. Medicis attempted to market the product in Canada, but due to the very mixed reaction, the marketing effort was not successful and it was ultimately withdrawn. Although Q-Med claims to have taken steps to improve the product, we understand that recent trials in Australia also produced deeply suboptimal outcomes. Because of the many problems with SubQ, I am personally doubtful that SubQ could obtain FDA approval and, therefore, I consider SubQ to be a failed product.

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assist the Court in applying the relevant contractual provisions.

Bio-Stimulating Particle Fillers.

12. In August 2004, the FDA approved the use of Sculptra, or poly-L-lactic acid, a product manufactured by Dermik Pharmaceuticals, which conducts the North American business of Aventis Dermatology, the global dermatology unit of Sanofi-Aventis. In July 2011, Valeant acquired Dermik, as well as the worldwide rights to Sculptra. As I set forth below, Sculptra works in a different way than HA products. Sculptra adds volume to the face by adding fluid to reconstitute or reframe the sculpture of the face. Where HA will fill up wrinkles, Sculptra may be used to substantially augment areas affected by facial atrophy or loss.

Differences Between Hyaluronic Acids and Bio-Stimulating Particle Fillers.

13. There are important differences between a volumizing product such as Sculptra, and HAs, such as Restylane and Perlane. As a consequence of their different chemical properties, the products work differently and have different effects on patients.

14. Sculptra is delivered to the patient through injections on each side of the face. Once injected, Sculptra creates a form of molecular scaffolding under the skin and stimulates collagen production. After several months, the body produces collagen that fills in areas of facial fat loss. Sculptra provides a gradual and significant increase in skin thickness, improving the appearance of folds and sunken areas.

15. HA, on the other hand, is a filler used to treat facial wrinkles and folds, as well as to perform lip augmentation. (In contrast, Sculptra may not be used on the lips; it has the potential to cause bumps on the surface of the skin and must be injected more deeply.) HA does not rely on the stimulation of collagen production in the

patient. The effects of HA are more immediate than the bio-particle fillers such as Sculptra. HA products such as Restylane tend to appeal to patients who seek more dramatic, immediate change.

16. There are also significant differences in how the products are administered that affect the decision of doctors and patients as to whether to use an HA or bio-particle filler. For instance, Sculptra is a synthetic freeze-dried powder that needs to be reconstituted with a liquid solution and refrigerated. Reconstituting the product takes a minimum of 2 to 3 hours, time that is required to enable the powder to be dissolved sufficiently to pass comfortably through a syringe. Because the prescribing dermatologist must reconstitute a certain amount of the product, if he or she does not have enough patients who will use Sculptra in a short period of time, the reconstituted solution must be discarded. HA, on the other hand, is a naturally occurring molecule in the human body, and the synthetic product exists as a gel-filled device. It does not require reconstitution or refrigeration like Sculptra.

17. The duration of the product effects further serves to distinguish the two classes of products. Sculptra is a semi-permanent product, which lasts approximately two years. Because of its long-lasting effects, it appeals to patients who are willing to sacrifice slower-acting gradual effects for fewer injections. Due to its longer-lasting presence in the face, the most common side effect is the development of nodules under the skin, which can lead to a granuloma, lumps that can be seen or felt beneath the skin.

18. An initial HA injection, on the other hand, lasts for only approximately six months and then is absorbed into the body, leading to no ill effects. Although subsequent injections of HAs have longer duration, they do not approach the

duration of Sculptra. Thus patients using the HA product, because of its shorter lifespan, require more frequent treatment to maintain the consistent effects of the product.

19. All of these factors—the differing results, treatment methods and patient experiences and pricing points—support my conclusion that HA products such as Restylane, on the one hand, and bio-particle products such as Sculptra, on the other, are better seen as complementary products rather than competitive ones.

20. My conclusion is underscored by the fact that the two products are frequently prescribed together. For example, Sculptra can be used to replace volume loss in certain areas of the face, such as the cheeks or jawline, while HA can be used on the same patient in areas where Sculptra cannot be used, such as the lips or corners of the mouth (because of concerns about leaving bumps).

Similar FDA Indications Do Not Mean Products Are Directly Competitive.

21. I understand Q-Med to be arguing that the direct competition between Restylane and Sculptra is proven by the fact that both fillers have FDA indications for use in the nasolabial folds (the "laugh lines" from the corner of the nose to the corner of the mouth). I disagree.

22. Restylane was the first modern injectable dermal filler approved by the FDA. Entries to the market subsequent to Restylane, including Sculptra, applied to the FDA using the same nasolabial indication for which Q-Med received approval. It is misleading to suggest, however, that simply because Sculptra and Restylane may both be indicated for nasolabial use that they are "directly competitive." It was to Sculptra's benefit to apply for approval for nasolabial use, because it could rely on the same regulatory pathway for approval that the FDA first accepted with Restylane, thereby

expediting the approval process. But FDA indications only set forth how the products are approved, not how they are actually used in the market or what drives consumer behavior in relation to the products. Although the products are approved for a certain FDA indication, after the products are sold they frequently are used for other purposes—what are commonly referred to as "off-label" uses.

23. Sculptra itself is, in fact, an excellent example of this. It was initially developed and approved in 2004 for use in patients suffering from facial atrophy or loss of facial volume due to effects of the human immunodeficiency virus ("HIV"). Attached hereto as Exhibit B is a true and correct copy of the initial FDA approval letter. Almost immediately, however, dermatologists began to use Sculptra for off-label cosmetic use in immune-competent patients. It was not until 2009 that Sculptra ultimately received FDA approval for general cosmetic use. Attached hereto as Exhibit C is a true and correct copy of the 2009 FDA approval letter.

24. Although Sculptra does have an indication for nasolabial folds, my understanding is that the product is rarely, if ever, the product of first choice for treating such conditions. To the contrary, its most common use is as a volumizer to add mass, generally, to faces that have become gaunt or hollowed out for various reasons—in particular the cheek and jaw line. By contrast, HA products such as Restylane are the filler of choice for filling in the laugh lines that are a common byproduct of aging.

Medicis Does Not Have Q-Med Trade Secrets Concerning Restylane Products.

25. The Declaration of Mr. Langö suggests that Q-Med has provided Medicis with trade secret information relating to the Restylane family of products and

that the merger with Valeant somehow will put Valeant in possession of important trade secret information.

26. I disagree. Medicis does not have, nor has it ever had, access to Q-Med's formulation and/or manufacturing trade secrets. Although we have received some technical reports on testing, we have never received information concerning the manufacture of Q-Med's products. Although I have toured Q-Med's factories, I was prohibited from accessing areas where sensitive information could be ascertained. Indeed, Q-Med has never shared with me or anyone else at Medicis information that would allow Medicis to engineer or manufacture Restylane products. Although I have worked closely with representatives of Q-Med in connection with clinical trials and regulatory approval processes, and may have certainly come across some non-public information in those efforts, Q-Med has consistently guarded the important details concerning the production process for, and makeup of, the Restylane products. Indeed, I am confident that if anyone at Medicis had such trade secrets it would be me or Steven Newhard, Senior Vice President, Quality and Technical Services. Having conferred with Mr. Newhard, I established that he, like I, has no such information.

27. Among other matters, I do not have access to the details of the chemical reaction that enables Restylane to achieve the results that it does, beyond what is generally known in the marketplace. I do not know the required pH level, the required concentrations, the required size of the reactor vessel, the required temperature to prepare the products, how long the chemical reaction is continued, how to stop the reaction, how to transfer the product, or the details of terminal sterilization. These are the types of details that would constitute the products' trade secrets. In my experience, Q-Med has

carefully guarded these trade secrets from Medicis. All I know is what anyone skilled in the art could learn from the common literature.

Dated: Scottsdale, Arizona
November 14, 2012

Mitchell S. Wortzman, Ph.D.